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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,749	08/23/2005	Dong Huang	13198.0003U1	6075
23859	7590	10/11/2006	EXAMINER	
NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915				CLARK, AMY LYNN
		ART UNIT		PAPER NUMBER
		1655		

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/517,749	HUANG, DONG	
	<b>Examiner</b>	<b>Art Unit</b>	
	Amy L. Clark	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 13 December 2004.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-36 are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ .  | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-12, drawn to a composition comprising an activity-enhancing amount of one or more saponins in combination with one or more sapogenins and having an enhanced anti-cancer effect.

Group II, claims 13, 15-20 and 36, drawn to a pharmaceutical composition for the treatment of cancer, comprising a therapeutically effective amount of the composition according to claim 1, and a pharmacologically acceptable carrier.

Group III, claims 14 and 31-35, drawn to a non-pharmaceutical composition for the treatment of cancer, comprising a therapeutically effective amount of the composition according to claim 1, and a pharmacologically acceptable carrier.

Group IV, claim(s) 21-29, drawn to use of the composition according to claim 1 for the treatment of cancer in a mammal.

Group V, claim(s) 30, drawn to a pharmaceutical kit for the treatment of cancer in a mammal comprising the composition according to claim 1 and one or more containers.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Claim 1, at least, is anticipated by or obvious over Empie et al. (US Patent Number 6,395,279 B1) because Empie teaches a composition for treating cancer comprising two or more fractions refined from plant matter such as saponins and sapogenins (See Abstract). Consequently, the special technical feature which links the claims does not provide a contribution over the prior art, so unity of the invention is lacking.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Group I:

Specie A: elect one saponin and sapogenin from Claim 2.

Specie B: elect one source of saponins and sapogenin from Claim 7 or Claim 12.

If Specie B is elected from Claim 7, further elect one specie of plant from the genus *Panax* from Claim 9, 10 or 11.

Group II:

Specie A: elect one form of administration from Claim 15, 16 or 17.

Group III:

Specie A: elect one form of administration from Claim 31, 32 or 33.

Group IV:

Specie A: elect one type of cancer from Claim 22, 23 or 24.

If Specie A is elected from Claim 24, further elect one multi-drug resistant cancer from Claim 25 or 26.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims

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subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

**Group I:**

Specie A: drawn to claims 2-6.

Specie B: plant derived saponins and sapogenins drawn to claims 7-11, synthetic saponins and sapogenins drawn to claim 12.

**Group II:**

Specie A: oral administration drawn to claim 15, injectable administration drawn to claim 16 and topical administration drawn to claim 17.

**Group III:**

Specie A: oral administration drawn to claim 31, injectable administration drawn to claim 32 and topical administration drawn to claim 33.

**Group IV:**

Specie A: cancer elected from claim 22 is drawn to claim 22, cancer elected from claim 23 is drawn to claim 23, cancer elected from claim 24, drawn to claims 24-26.

The following claim(s) are generic: Claims 1, 7, 13, 14, 21 and 24.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are independent or distinct because the saponins and sapogenins in claim 2, the plant derived saponins and sapogenins of claim 7 and the synthetic saponins and sapogenins drawn of claim 12, the forms of administration in claims 15-17 and 31-33,

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and the types of cancer in claims 22-26 are distinct both physically and functionally from each other and a search for saponin and sapogenin, one form of administration and one type of cancer is not co-extensive with a search for another.

\* Applicant is advised that the cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site ([www.uspto.gov](http://www.uspto.gov)), from the Office of Public Records and from commercial sources. Should you receive inquiries about the use of the Office's PAIR system, applicants may be referred to the Electronic Business Center (EBC) at <http://www.uspto.gov/ebc/index.html> or 1-866-217-9197.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy L. Clark whose telephone number is (571) 272-1310. The examiner can normally be reached on 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

*Michele C. Flood*  
MICHELE FLOOD  
PRIMARY EXAMINER

Amy L. Clark  
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Amy L. Clark  
September 19, 2006